

Remarks

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider and withdraw the outstanding rejections.

Claim Status

Upon entry of the foregoing amendments, independent claim 60 is pending in the application. Claim 60 has been amended. Support for the claim amendment may be found throughout the Specification. See, e.g., page 5 at paragraph [0037] of the published application. Thus, no new matter is added by way of this amendment, and its entry is respectfully requested.

Claim Rejections Under 35 U.S.C. § 112

Claim 60 is rejected under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement.

The Examiner asserts that “the specification provides no support for the amendment such that ‘said composition is not diluted more than 2x.’” See Action at page 4.

Without acquiescing to the Examiner’s assertions, in an effort to advance prosecution, Applicants have amended claim 60. Thus, the written description rejection with regard to this claim is moot. Applicants request that the rejection under 35 U.S.C. § 112, first paragraph be withdrawn accordingly.

Claim Rejections Under 35 U.S.C. § 103

Claim 60 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Holmes (WO 95/00664), in view of Gelfand (US Patent No. 5,618,703), Hoeltke (US Patent 5,814,502) and Scalice (US Patent 5,338,671). Applicants respectfully traverse this rejection.

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art. See *In re Piasecki*, 745 F.2d 1468, 1471-73, 223 USPQ 785, 788 (Fed. Cir. 1984). To meet this burden, the Examiner must show that each claim element is taught or suggested by the prior art. See *In re Royka*, 490 F.2d 981 (CCPA 1974); *In re Glaug*, 283 F.3d 1335 (Fed. Cir. 2002); *In re Rijckaert*, 9 F.3d 1531 (Fed. Cir. 1993).

Amended claim 60 relates to a method for nucleic acid synthesis, sequencing or amplification, involving (a) taking from a temperature between -20°C to +4°C a composition comprising a thermostable DNA polymerase, a deoxynucleoside triphosphate, at least one antibody that binds the thermostable polymerase, and a buffer salt, wherein the polymerase to antibody ratio is between 1:1 and 1:10; and then (b) adding nucleic acid molecules to the composition.

The references cited in the Office Action (i.e., Holmes, Gelfand, Hoeltke and Scalice) do not render the claimed method obvious under 35 U.S.C. §103. Holmes teaches methods of performing multiple amplification reactions using different nucleic acid primer pairs and templates. As recognized in the Office Action, Holmes does not teach a master mix, a master mix containing a polymerase-binding antibody, or the use of such a master mix after storage at a temperature between -20°C to +4°C. See Office Action dated April 16, 2007 at page 3.

Consequently, the Office Action offers Gelfand for its disclosure of methods for performing multiple reverse transcription reactions wherein a master mix is used. The Office Action further offers Hoeltke for its disclosure of nucleic acid-labeling methods using master mixes said to be stable at temperatures between -20°C to +4°C. Finally, in attempt to cure the combined deficiencies of Holmes, Gelfand, and Hoeltke, the Office Action offers Scalice for its disclosure of master mixes containing antibodies specific for a thermostable DNA polymerase.

While Gelfand, Hoeltke and Scalice do teach the use of master mixes, none of these references disclose a method as is presently claimed: i.e., where a master mix comprising a thermostable DNA polymerase, a deoxynucleoside triphosphate, an antibody at a polymerase:antibody concentration ratio between 1:1 and 1:10, and a buffer salt is taken from a temperature between -20°C to +4°C; and then nucleic acid molecules are added to the mix.

Specifically, Scalice discloses master mixes containing polymerases and polymerase-binding antibodies, but does not disclose such master mixes where the polymerase to antibody ratio is between 1:1 and 1:10. See Scalice, e.g., at Examples 1-3.

Thus, none of the cited references, alone or in combination, disclose the claimed method. Accordingly, a *prima facie* case of obviousness has not been established and Applicants respectfully request that the rejection of claim 60 under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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